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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,151	10/27/2003	Stephen C. Porter	03-116 (US01)	6462
41696 7590 06/28/2007 VISTA IP LAW GROUP LLP 12930 Saratoga Avenue Suite D-2 Saratoga, CA 95070			EXAMINER HOUSTON, ELIZABETH	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 06/28/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/695,151

Applicant(s)

PORTER, STEPHEN C.

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30, 32-38 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30, 32-38, 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/27/07 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 32 from which claim 33 depends requires that the active element radially contract in order to cause the coil to retain its shape. This implies that there would be little or no axial elongation. Claim 33 requires that the active element be a shape memory alloy or polymer. Examiner is assuming that the only way radial contraction (or decrease in diameter) would occur in this instance would be if

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the shape memory material was in the form of a coil. If the shape memory were a coil that radially contracted, it would inherently elongate in the axial direction and therefore would not cause the coil to substantially retain its shape when deployed. There is no further explanation in the specification to help one to understand the combination of limitations.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1, 2, 4-6, 7, 10, 11, 14-18, 21, 30 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Martinez (US 2004/0098028).**

6. Martinez discloses vaso-occlusive device comprising an elongate occlusive member that is a helically wound coil defining a longitudinal axis (13) having an elongate axial lumen and an active element (12) having a pre-deployment configuration carried entirely within the lumen (fig. 2). No portion of the pre-deployed active element is located outside of the lumen. The active element is configured to radially expand to a

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deployed configuration without application of mechanical force when placed in the body to cause the occlusive member to retain its shape (Figs. 3 and 4). The active element is secured to the occlusive member at one or both ends and at one or more locations along the length of the occlusive member (coil 13 along the length and 14, 15 at the ends; Para [0036]). The active element is a hydrogel comprising polysaccharide with a cross linking polymer (Para [0024]). The active member has an elongate shape when it is undeployed (Fig. 2) and a coil shape when it is deployed (Fig. 3). The active element when in the body may be expanded to have a cross sectional dimension that is at least 100% of the internal diameter of the occlusive member and may be expanded to between 110% and 200% of the internal diameter of the occlusive member (Para [0037]).

**7. Claims 1, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zadno-Azizi (USPN 6,231,588).**

8. Zadno-Azzizi discloses an occlusive device (114) comprising an elongate occlusive member having a longitudinal axis and an elongate axial lumen (134) and an active element (130) entirely within the lumen configured to expand upon deployment without application of mechanical force to cause the occlusive member to retain its shape when deployed. The active element is a shape memory alloy or shape memory polymer (Col 4, lines 36-58).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**10. Claims 1-3, 27, 32-35, 38 rejected under 35 U.S.C. 103(a) as being unpatentable over Martinez (US 2004/0098028) in view of Rosenthal (USPN 7,066,904).**

11. Martinez discloses the vaso occlusive device as stated above. Martinez does not disclose that the hydrogel is configured to contract to a deployed configuration when placed in a body.

12. Rosenthal discloses the use of hydrogel for delivering drugs. Rosenthal disclose that the hydrogel can expand or contract in order to release the drug (Col 6, line 55-64). The active element is a polymer hydrogel that is swollen with an aqueous ionic solution that will diffuse out of the gel upon contact with blood (Col 2, lines 32-57). Regarding claim 33, the active element is a polymer. The polymer is thermoresponsive.

13. It would have been obvious to one having ordinary skill in the art at the time of the invention to use a hydrogel for drug delivery. Martinez discloses that the intermediate element (12) (the hydrogel) can be used to deliver drugs. Rosenthal offers the details for delivering the drug in that the hydrogel can be expanded or contracted to release the drug. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

**14. Claims 8, 9, 22-26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinez in view of Sawhney (US Pub 2001/0046518).**

**15. Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinez in view of Rosentahl as applied to claim 32 above and further in view of Sawhney (US Pub 2001/0046518).**

16. Martinez and Martinez in view of Rosenthal disclose the invention substantially as claimed as stated above except for the material that makes up the hydrogel.

17. Sawhney discloses a hydrogel used for delivery of therapeutic agents. The hydrogel comprises polypropylene glycol or poly-hydroxyalkyl methacrylate (Para 37,38). The hydrogel comprises polysaccharides, hyaluronic acid or heparin (Para 35). The hydrogel further comprises chemical cross-linking agents (Para 31). The hydrogel is thermoresponsive (Para 40). The hydrogel comprises a polyelectrolyte (Para 38) and undergoes an ionic concentration induced shape change (Para 40). The active element can be a fiber (Para 37 and 62), which undergo a thermally induced phase change or a pH induced phase change (Para 40). The active element expands within about 10-20 minutes of being placed in a body and will increase to between 110 and 200 percent of the internal diameter of the coil (Para 28).

18. As to claims 27 and 38, when the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the

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reference discloses all the limitations of a claim (in this case, *the hydrogel is comprised of a polyelectrolyte*) except for a property or function (in the present case, *the solvent will diffuse out of the gel upon contact with the blood causing the active element to contract*) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

19. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the materials disclosed by Sawhney into the hydrogel of Sepetka and Jones. Sawhney provides the motivation in that the hydrogel disclosed provides advantages over prior art hydrogels. For example, they undergo a relatively large degree of swelling and hydrate relatively quickly with out degradation of mechanical properties (Para 23, 25).

### ***Response to Arguments***

20. Applicant's arguments with respect to claims 1-30, 32-38 and 40 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh 

  
(JACKIE) TAN-UYEN HO  
PRIMARY EXAMINER  
6/22/07